

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

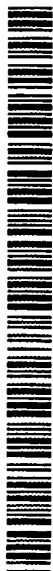


(43) International Publication Date
8 February 2001 (08.02.2001)

PCT

(10) International Publication Number
WO 01/08602 A1

- (51) International Patent Classification⁷: A61F 2/06, A61M 25/00
A. [US/US]: 382 Dunstable Road, Tyngsboro, MA 01879 (US).
- (21) International Application Number: PCT/US00/20574
(74) Agent: PERULLO, John, F.; Kirkpatrick & Lockhart LLP, 75 State Street, Boston, MA 02109-1808 (US).
- (22) International Filing Date: 28 July 2000 (28.07.2000)
- (25) Filing Language: English
(81) Designated States (national): CA, JP, MX, US.
- (26) Publication Language: English
(84) Designated States (regional): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
- (30) Priority Data: 60/146,470 30 July 1999 (30.07.1999) US
Published:
— With international search report.
- (71) Applicant (for all designated States except US): C. R. BARD, INC. [US/US]; 730 Central Avenue, Murray Hill, NJ 07974 (US).
- (72) Inventor; and
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.
- (75) Inventor/Applicant (for US only): GAMBALE, Richard,



WO 01/08602 A1

(54) Title: IMPROVED IMPLANT ANCHOR SYSTEMS

(57) Abstract: The present invention provides implant devices configured to become anchored within tissue so that they do not migrate despite experiencing aggressive migration forces applied by the highly dynamic movement of muscle tissue that surrounds them. Additionally, methods for placing the devices so that they remain securely anchored within the tissue are provided. The devices are comprised of a flexible body, preferably formed from a helical wound spring. In a preferred embodiment the spring is wound from a ribbon-like filament having series of barbs or ridges formed along the proximal facing edge of the wound ribbon. The ribbon-like filament may be etched from a flat sheet of material, having barbs formed along one edge. The filament may then be wrapped into a helical coil shape to take the form of an implant having barbs formed along the proximally facing edge of each coil to resist migration.

- 1 -

IMPROVED IMPLANT ANCHOR SYSTEMS

Field of the Invention

This invention relates to tissue implant devices and methods of their use. In particular, the devices and methods concern systems for anchoring the implants in tissue so that they do not migrate after implantation.

Background of the Invention

There are a variety of applications for tissue implant devices in the human body. Such applications include electrical pacing leads or other tissue monitoring devices or tissue support structures such as endoluminal stents. A device implanted in tissue may experience migratory forces applied by movement of the surrounding tissue into which the device has been implanted. Migration is especially a problem in muscle tissue that regularly contracts and relaxes around the device. Because the device is static and is relatively inflexible, rather than absorbing the forces applied by the tissue, those forces act on the device to move it in the tissue. Migration of the device ultimately may lead to ejection of the device from the tissue. An ejected device could prove harmful to a patient if it enters the blood stream and blocks blood flow to a critical organ such as the brain.

Perhaps the most regular aggressive migratory forces created by muscle tissue may be experienced by implant devices which are placed in heart tissue. Because the heart muscle regularly contracts and relaxes in an exaggerated fashion to pump blood through the ventricle, implant devices located within that tissue have significant forces applied upon them. For example, the myocardial tissue comprising the exterior wall of the heart at the left ventricle may increase in thickness by forty to sixty percent with each contraction. Conventional methods of anchoring a device to tissue such as by stapling or suturing prove difficult in applications where there is exaggerated and constant movement of the subject tissue because it is difficult to accurately apply a suture or staple to the intended location.

Implant devices for the heart have been disclosed in U.S. patent 5,429,144 (Wilk) and in U.S. patent 5,810,836 (Hussein et al.) for the purpose of restoring blood flow to the tissue of the heart. Conventional treatments of restoring blood flow to

- 2 -

heart tissue such as coronary artery bypass grafting have been supplanted in recent years by various methods of transmyocardial revascularization (TMR). TMR methods include creating channels into tissue of the heart either by needle acupuncture or coring with a hypodermic tube or by laser or mechanical ablative methods. Hussein and Wilk attempt to maintain the patency of such channels by a placement of a mechanical implant device to the heart tissue to support an open pathway through which blood may flow. The Hussein patent discloses several stent embodiments that are delivered through the epicardium of the heart into the myocardium and positioned to be open to the left ventricle.

Due to the exaggerated migration forces experienced by an implant device in heart tissue as described above, it would be desirable to provide devices and methods for securely anchoring an implant in an associated dynamic region of tissue. It is a general object of the present invention to provide such an anchoring system for tissue implants, especially those intended for placement in the heart that may be useful for revascularization of the heart tissue by various mechanisms.

Summary of the Invention

The present invention provides implant devices configured to become anchored within tissue so that they do not migrate despite experiencing aggressive migration forces applied by the highly dynamic movement of muscle tissue that surrounds them. Additionally, methods for placing the devices so that they remain securely anchored within the tissue are provided. The devices are comprised of a flexible body, preferably formed from a helical wound spring. In a preferred embodiment the spring is wound from a ribbon-like filament having series of barbs or ridges formed along the proximal facing edge of the wound ribbon.

The devices of the present invention may be delivered to the intended tissue location percutaneously, through a catheter based system, transthoracically or surgically. Although the inventive devices and methods can be applied to implants intended for use in any region of the body, it is believed that the anchor systems are especially useful as applied to implant devices for the heart configured to treat ischemia. Flexible implant devices may be configured to promote angiogenesis

- 3 -

through a variety of mechanisms examples of which are described in detail in pending U.S. patent application serial nos. 09/164,173, 09/211,332 and 09/299,795.

Generally, the spring implant devices may be considered to have a body having proximal and distal portions. In the present application, proximal is understood
5 to mean the direction leading external to the patient and distal is understood to mean
any direction leading internally to the patient. The implant devices discussed herein
are delivered into the tissue in a distal direction so that the body is implanted within
the tissue and the proximal end of the device is approximately flush with the tissue
surface or slightly submerged under the surface. The configuration of the barbs to
10 resist migration of the device proximally back out of the tissue. Additionally, the barbs
may serve to resist rotational movement of the device so that it does not "unscrew"
out of the tissue.

In an embodiment of the invention, a flexible implant device formed from a
helical spring body may be formed from a filament having a non-circular cross-
15 section. For example, a filament having a rectangular cross-section may serve to
prevent migration through the tissue in the axial direction by several mechanisms.
When the helical coil is wound such that the major axis of the rectangular cross-
section is substantially perpendicular to the longitudinal axis of the body of the device
greater axial flexibility is imparted to the spring, while maintaining sufficient radial
20 stiffness to resist crushing by the tissue, than would be possible with a round cross-
sectional filament material. Increased axial flexibility of the device permits it to move
with surrounding tissue, absorbing forces that would otherwise tend to push the
device out of position in the tissue. Additionally, as surrounding tissue herniates
through the individual coils of the device, the orientation of the major axis of the
25 rectangular cross-section of the filament to be perpendicular to the longitudinal axis of
the device presents a larger surface area engaging the tissue to resist axial migration.

Alternatively, the major axis of the rectangular cross-section filament may be
oriented at an angle that is acute to the longitudinal axis of the device, so that the
filament is canted in the proximal direction, to facilitate insertion of the device in the
30 distal direction during implantation into the tissue. The canted orientation of the
rectangular cross-sectional filament still provides the flexibility benefits of the

- 4 -

perpendicular orientation discussed above and may enhance anchoring capability by presenting a leading proximal facing edge that serves to grip into tissue.

Barbs formed on the proximally facing edge of the finished may be formed on the ribbon prior to winding into its coiled shape. Preferably, the ribbon is formed
5 having barbed shapes along at least one edge of the ribbon by an etching process. A number of ribbons may be etched on a sheet of suitable material, such as stainless steel, at once. After the ribbons are formed on the sheet of material, they may be individually detached from the sheet and wound on a spring winding machine to form a coil by conventional spring winding techniques.

10 A variety of filament materials may be used such as surgical grade stainless steels. Other materials may be used to vary the modulus of elasticity of the filament. Additionally, flexibility of the coil implant may be varied along the length of the coil, not only by varying spacing between coils and diameter of the filament along its length, but also by using two or more different filament materials along the length of the
15 filament that have different moduli of elasticity.

It is an object of the present invention to provide a tissue implant device that resists migration from the tissue into which it is implanted by offering improved anchoring capability.

It is another object of the present invention to provide a tissue implant device
20 having an anchor mechanism that is easy to integrate into small mechanical devices.

It is yet another object of the present invention to provide an implant device that resists migration by its inherent flexibility and ability to absorb migratory forces exerted by surrounding tissue.

It is another object of the invention to provide an implant device that utilizes an
25 anchoring mechanism that is submerged beneath the surface of the tissue into which the device is implanted.

It is yet another object of the invention to provide a method of implanting a tissue implant device so that it remains anchored in the tissue.

- 5 -

Brief Description of the Drawings

The foregoing and other objects and advantages of the invention will be appreciated more fully from the following further description thereof, with reference to the accompanying diagrammatic drawings wherein:

- 5 FIG. 1 is a side view of an alternate embodiment of the tissue implant device;
 FIG. 2 is a partial sectional view of the tissue implant device shown in FIG. 13;
 FIG. 3 is a partial sectional view of a variation of the tissue implant device
 shown in FIG. 2;
 FIG. 4 is a side view of a preferred embodiment of the tissue implant device
10 having barbs;
 FIG. 5 is a side view of an alternate embodiment of the tissue implant device
 having barbs;
 FIG. 6 is a top view of a sheet of material having a plurality of etched ribbon
 forms through out its surface.
15 FIG. 7 is a magnified view of one of the etched ribbon forms on the sheet
 shown in FIG. 6;
 FIG. 8A. is a side view of a tissue implant device delivery system;
 FIG. 8B is a detailed side view of the distal end of the tissue implant device
 delivery system; and
20 FIG. 8C is a detailed side view of the distal end of the tissue implant device
 delivery system carrying an implant.

Description of the Illustrative Embodiments

25 The implant devices of the present invention are particularly useful in treating
 ischemic tissue such as that often occurs in a myocardium of the heart. The implant
 device may be inserted into the myocardium through the epicardial surface at an entry
 site such that the device extends the majority of the thickness of the myocardium
 towards endocardial surface.

30 FIG. 1 shows an embodiment of a tubular implant device. The canted coil
 device 40 is formed from a filament 42 of rectangular cross-section such as a strand
 of flat wire. As shown in FIG. 2, the coil is formed so that the major cross-sectional

- 6 -

axis 47 of the rectangular wire is oriented at an acute angle to the longitudinal axis 50 of the coil 40. The orientation gives each turn 46 of the coil a projecting edge 44, which tends to claw into tissue to serve as an anchoring mechanism for the device.

FIG. 3 shows a segment of a wrapped ribbon implant embodiment. The
5 implant 60 is formed by a filament of a rectangular cross-sectional filament around a ribbed mandrel. In the present embodiment, the major axis 47 of the rectangular cross-section ribbon is oriented substantially perpendicular to the longitudinal axis 50 of the implant, as is shown in FIG. 3. In this configuration, the major axis 47 of the coils 42 of the rectangular ribbon do not extend radially from the longitudinal axis 50
10 of the implant 40 at an acute angle. With greater coil surface area extending away from the longitudinal axis of the implant, the implant is believed to be more stable and less likely to migrate once implanted within the myocardium. The implant is preferably formed from 316 stainless steel rectangular cross-section forming wire. Preferred dimensions for the rectangular cross-section filament are on the order of .003 inches
15 to .005 inches for the minor axis width and .015 to .018 inches for the major axis.

FIG. 4 shows a preferred embodiment of the wrapped ribbon device 62 having a plurality of barbs 64 formed on the proximally facing edge 66 of the ribbon. The device may only have one barb, but a plurality of barbs is preferred. Each barb has a tapering penetrating shape configured to claw into tissue to resist migration of the
20 device. The barbs may be a variety of shapes such as the curved shape shown in the figures or a sharp pointed shape (not shown). Barbs 64 formed on the spring embodiment shown in Figure 1 tend to project radially outward from the longitudinal axis of the device at an acute angle, as shown in Figure 4. The radial projection of the barbs may help to anchor the implant within tissue.

25 Alternatively, as shown in Figure 5, the spring device 68 may have coil 70 oriented such that the major their axis is parallel to the longitudinal axis of the device and barbs 64 are curved radially outward from the proximally facing edge 72 of each coil 70. The barbs may be curved by bending prior to wrapping of the ribbon into a coil form.

30 Ribbon material having integrally formed barbs may be formed by variety of methods; however, chemically etching of the ribbon having barbed shapes is

- 7 -

preferred. FIG. 6 shows a top view of a sheet 76 of material having a plurality of ribbon forms 78 that have been etched through its surface. FIG. 7 shows a magnified view of a single ribbon form 78 comprising a linear ribbon form 79 of a plurality of barb 64, which will ultimately be wrapped into the spring device. Each form 78 remains joined to the sheet 76 after etching by links 77. Ribbon forms are preferably created by a photo etching process. In this process, a photo resistant coating is first applied over the entire sheet of material. Preferably a sheet of stainless steel material is used to having a thickness equivalent to the desired thickness of the final ribbon product as has been defined above. After application of the coating a template having the desired pattern of shapes (a plurality of ribbons having barbs with spare material between each ribbon form) is placed over the sheet. Next the sheet is applied to remove the protective coating from areas of the sheet where material is to be removed. The resultant sheet etchant protective coating only over areas where material is to remain. The sheet is then exposed to a chemical etchant which removes material from the sheet in the unprotected areas. The resultant 76 sheet shown FIG. 6 has numerous perforations where material has been removed the chemical etchant process provides a quick and economical way to form numerous pieces of ribbon stock having accurately formed barbs. The ribbon forms an easily finished sheet by breaking or cutting links 77. The ribbon may be wrapped in to the helical spring implant device as is described above.

_____The implant devices of the present invention may be delivered to their intended tissue location surgically. FIGS. 8A - 8C show an example of a surgical delivery device that may be used to deliver the implants into tissue such as that of the myocardium of the heart. The delivery device, shown in FIG. 8A, comprises an obturator 80 that includes a main shaft 82, by which it can be gripped and manipulated. The distal end 81 of the shaft 82 is shown in detail in FIG 8B and includes a reduced diameter device support section 84 having a sharp distal tip 86 adapted to pierce tissue. The diameter of the shaft segment 84 is such as to fit closely within the interior of the devices. The proximal end of the segment 84 terminates in a shoulder 88 formed at the junction of a proximally adjacent, slightly enlarged diameter portion 90 of the shaft. The distal end of the device support

- 8 -

segment 84 may include a radially projecting pin 92 dimensioned to project and fit between adjacent turns of the coils of a device. The pin 92 engages the coils in a thread-like fashion so that after the assembly has been inserted into the tissue, the obturator 80 can be removed simply by unscrewing the obturator to free it from the implanted coil. Alternatively, the obturator may be configured without the projecting pin 92 so that the device can be slipped on and off the obturator, without screwing. When an implant device 2 is mounted on the obturator 80, as is shown in FIG. 8C the proximal end of the device may bear against the shoulder 88, and the tail 28, if so equipped may extend along the segment 90 of the obturator.

10 In use, the intended tissue location is first accessed surgically, such as by a cut-down method. The obturator, with an implant device loaded on to segment 84, then may be advanced into the tissue to deliver the implant. The sharp tip pierces the tissue permitting the obturator and implant to be pushed inward into the tissue. In the example of delivery to the myocardium, the epicardial surface of the heart is accessed and penetrated by the obturator to deliver the implant. The shoulder 88 prevents proximal movement of the implant along segment 84 during delivery. Preferably, the distal end of the obturator is projected to, and slightly beyond, the endocardium to place the implant device. The obturator then may be unscrewed and separated from the implant device. If the obturator is configured without the pin 92, the obturator may be withdrawn directly from the device and the tissue. Simply applying light closure pressure to the epicardial puncture will cause the puncture hole to clot at the epicardium.

25 Generally, surgical grade stainless steels are used to fabricate the implant devices discussed above, but other materials having different moduli of elasticity such as nickel titanium alloys can be used.

From the foregoing it will be appreciated that the invention provides a novel approach to providing an anchoring system for implant devices. The devices and methods of the present invention are simple and easy to apply to a wide range of implant designs.

30 It should be understood however, that the foregoing description of the invention is intended merely to be illustrative thereof and that other modifications, embodiments

- 9 -

and equivalents may be apparent to those who are skilled in the art without departing from its spirit. Having thus described the invention what we desire to claim and secure by letters patent is:

- 10 -

Claims

1. A tissue implant device configured to resist migration in tissue comprising a flexible helical spring having at least one barb that engages surrounding
5 tissue.

2. An implant as defined in claim 1 wherein the at least one barb is proximally facing.

10 3. The implant as defined in claim 1 wherein the barb faces radially outward from the spring.

4. An implant as defined in claim 1 wherein the barb has a rounded contour.

15 5. An implant as defined in claim 1 wherein the at least one barb has a sharpened point configured for engaging tissue.

6. An implant as defined in claim 1 wherein the helical spring is formed
20 from a filament having a rectangular cross-sectional profile.

7. An implant device as defined in claim 6 wherein the helical spring comprises a plurality of coils, each having a proximally facing edge along which is formed a plurality of barbs.

25 8. An implant as defined in claim 1 wherein the spring is formed from a plurality of materials each having different moduli of elasticity.

9. An implant as defined in claim 1 wherein the spring is formed from
30 metal.

- 11 -

10. An implant as defined in claim 9 wherein the metallic material is stainless steel.
11. An implant as defined in claim 1 wherein the moduli of elasticity of the spring varies along its length.
12. An implant as defined in claim 1 wherein the spring is formed from a filament that has been etched from a flat sheet of material and wound into a spring configuration.
13. An implant as defined in claim 12 wherein at least one barb is formed into the filament during the etching process.
14. A method of forming a tissue implant device comprising:
forming a ribbon shaped form in a sheet of material by a photochemical etching process;
separating the ribbon formed from the sheet of material; and
wrapping the ribbon form into a helical coil shape, plastically deforming the ribbon so that it retains the coil shape.
15. The method as defined in claim 14 further comprising:
forming at least one barb shape on an edge of the ribbon forms so that the resultant coiled ribbon has at least one projecting barb along the edge.
16. A method as defined in claim 15 wherein at least one barb is formed along an edge that will be proximally facing after the ribbon is wrapped into a coil shape.
17. A method as defined in claim 15 wherein a plurality of barb shapes are formed along an edge of the ribbon form so that the resultant coil ribbon has a plurality of projecting barbs along one edge of the coil.

- 12 -

18. A method of forming a tissue implant device as defined in claim 15 further comprising forming a plurality of ribbons in a single sheet of material by photochemical etching process.

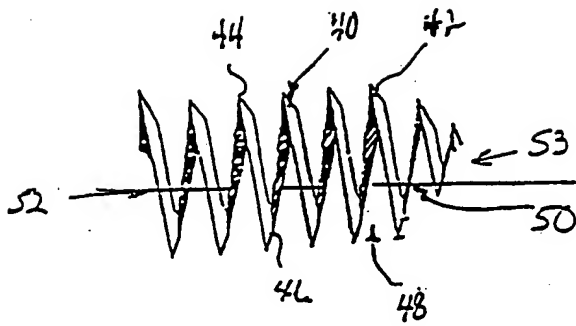


FIG. 1

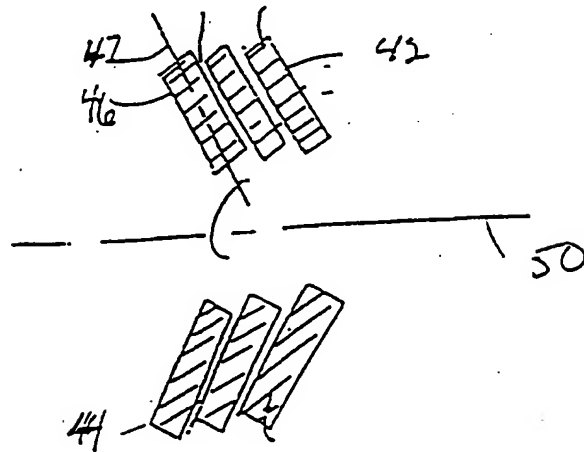


FIG. 2

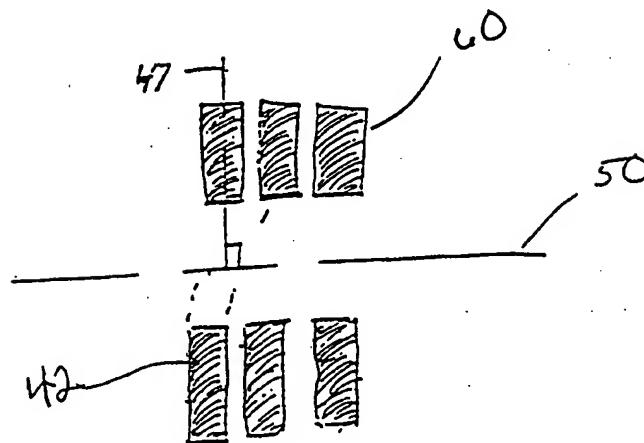


FIG. 3

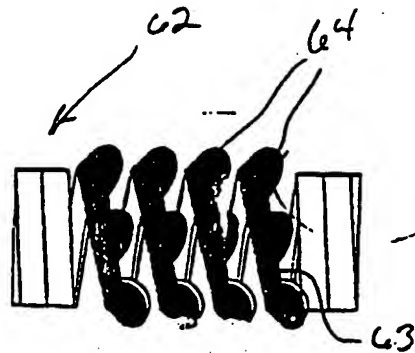


FIG. 4

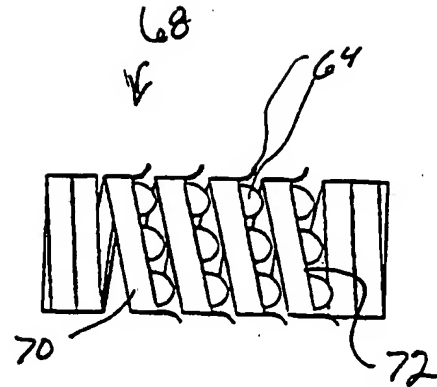


FIG. 5

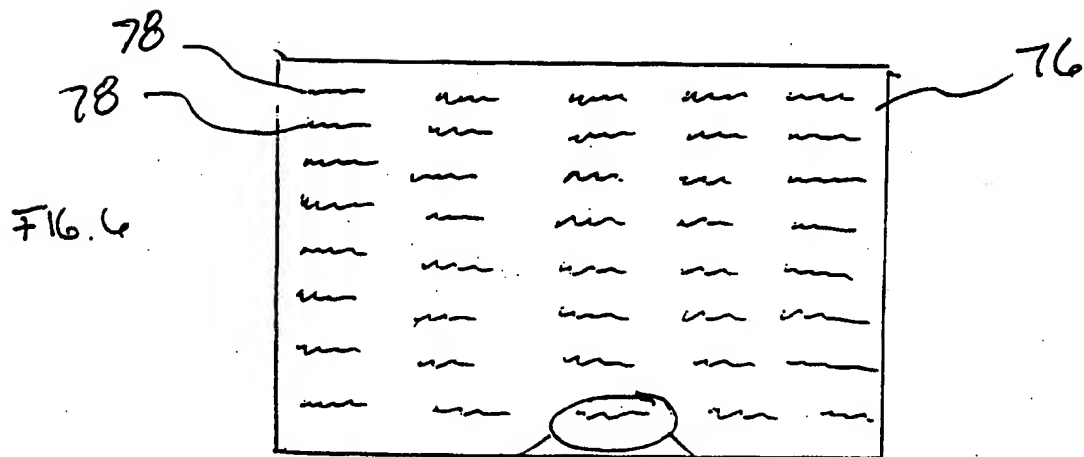


FIG. 6

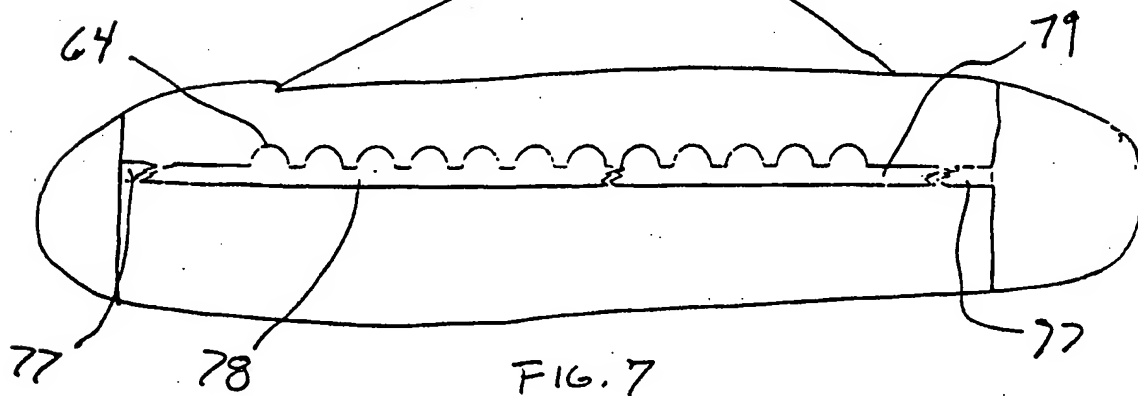


FIG. 7

FIG. 8A

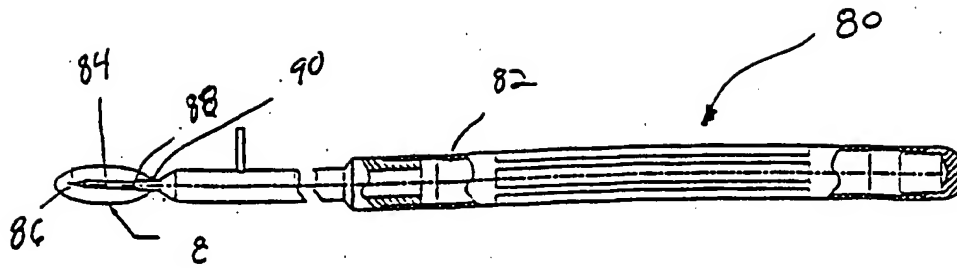


FIG. 8B

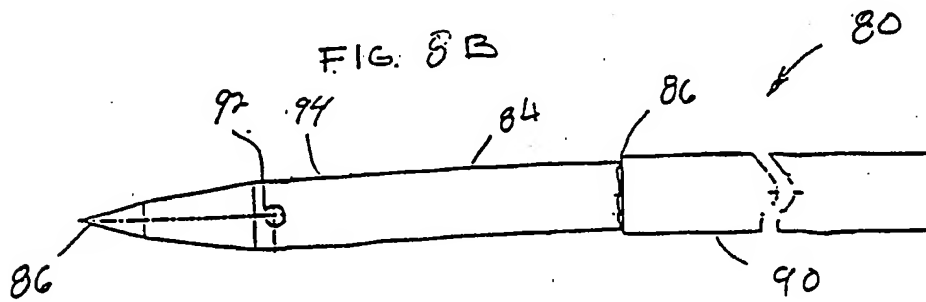
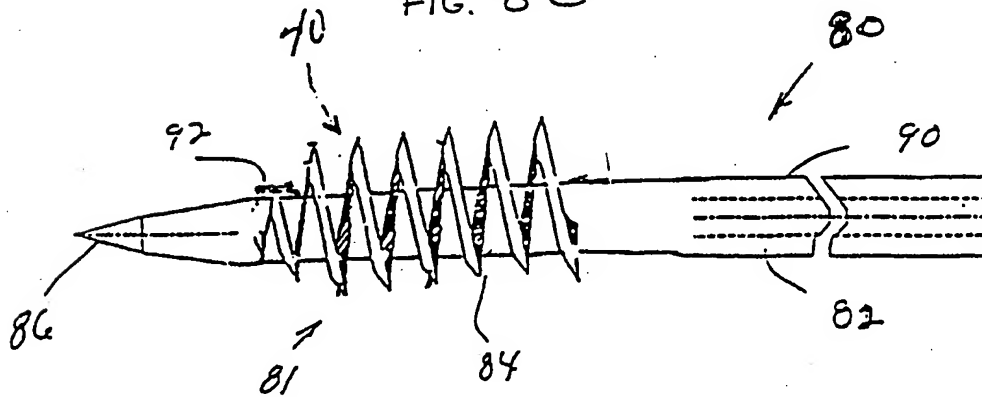


FIG. 8C



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/20574

A. CLASSIFICATION OF SUBJECT MATTER														
IPC(7) : A61F 2/06; A61M 25/00 US CL : 623/1.15, 1.22, 1.36, 901 According to International Patent Classification (IPC) or to both national classification and IPC														
B. FIELDS SEARCHED														
Minimum documentation searched (classification system followed by classification symbols) U.S. : 623/1.15, 1.22, 1.36, 901														
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched														
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) WEST-U.S. PATENTS														
C. DOCUMENTS CONSIDERED TO BE RELEVANT														
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.												
X -- Y	EP 0 876 803 A2 (C.R. BARD, INC) 11 November 1998, col. 2, lines 34-41; col. 2, line 52 - col. 3, line 29.	1-7, 9-10 ----- 8, 11-13, 15-18												
Y	US 5,833,699 A (CHUTER) 10 November 1998, col. 5, lines 39-64; col. 7, lines 39-49.	8, 11-18												
Y	US 5,370,683 A (FONTAINE) 06 December 1994, Abstract; col. 3, lines 21-32.	12-13												
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.														
<table border="0"> <tr> <td>* Special categories of cited documents:</td> <td>*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>*A* document defining the general state of the art which is not considered to be of particular relevance</td> <td>*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</td> </tr> <tr> <td>*E* earlier document published on or after the international filing date</td> <td>*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</td> </tr> <tr> <td>*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>*A* document member of the same patent family</td> </tr> <tr> <td>*O* document referring to an oral disclosure, use, exhibition or other means</td> <td></td> </tr> <tr> <td>*P* document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table>			* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	*A* document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone	*E* earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art	*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A* document member of the same patent family	*O* document referring to an oral disclosure, use, exhibition or other means		*P* document published prior to the international filing date but later than the priority date claimed	
* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention													
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone													
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art													
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A* document member of the same patent family													
O document referring to an oral disclosure, use, exhibition or other means														
P document published prior to the international filing date but later than the priority date claimed														
Date of the actual completion of the international search 18 OCTOBER 2000		Date of mailing of the international search report 16 NOV 2000												
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230		Authorized officer CHOON P. KOH Telephone No. (703) 305-1232												